

JM-009 CIP2

METHODS AND APPARATUS FOR A CURVED STENT

Reference To Related Applications

The present application is a continuation-in-part of U.S. patent application Serial No. 09/742,144, filed December 19, 2000, which is a continuation-in-part of U.S. patent application Serial No. 09/582,318, filed June 23, 2000, which claims the benefit of the filing date of International Application PCT/EP99/06456, filed September 2, 1999, which claims priority from German application 19840645.2, filed September 5, 1998.

Field of the Invention

The present invention relates to stents. More particularly, the present invention relates to stents having curvature, and that preferably have web structures configured to expand from contracted delivery configurations to expanded deployed configurations.

Background of the Invention

Various stent designs are known in the art. These stents form vascular prostheses fabricated from biocompatible materials. Stents are typically used to 5 expand and maintain patency of hollow vessels, such as blood vessels or other body orifices. To this end, the stent is often placed into a hollow vessel of a patient's body in a contracted delivery configuration and is subsequently expanded by suitable means, such as by a 10 balloon catheter or through self-expansion, to a deployed configuration.

A stent often comprises a stent body that is expandable from the contracted to the deployed configuration. A common drawback of such a stent is that 15 the stent decreases in length, or foreshortens, along its longitudinal axis as it expands. Such shortening is undesirable because, in the deployed configuration, the stent may not span the entire area inside a vessel or orifice that requires expansion and/or support. 20 Additionally, when implanted in tortuous anatomy, prior art stents may apply hazardous localized restoring forces to the vessels or orifices.

It therefore would be desirable to provide a stent that experiences reduced foreshortening during 25 deployment.

It also would be desirable to provide a stent that is flexible, even in the contracted delivery configuration.

It would be desirable to provide a stent having radial stiffness in the expanded deployed configuration sufficient to maintain vessel patency in a stenosed vessel.

5 It would be desirable to provide a stent having curvature adapted to reduce localized restoring forces.

Summary Of The Invention

In view of the foregoing, it is an object of the present invention to provide a stent that experiences 10 reduced foreshortening during deployment.

It is another object to provide a stent that is flexible, even in the contracted delivery configuration.

It is also an object to provide a stent having radial stiffness in the expanded deployed configuration 15 sufficient to maintain vessel patency in a stenosed vessel.

It is an object to provide a stent having curvature adapted to reduce localized restoring forces.

These and other objects of the present invention are 20 accomplished by providing a stent having a tubular body whose wall has a web structure configured to expand from a contracted delivery configuration to an expanded deployed configuration. The web structure comprises a plurality of neighboring web patterns having adjoining webs. Each web has three sections: a central section 25 arranged substantially parallel to the longitudinal axis in the contracted delivery configuration, and two lateral sections coupled to the ends of the central section. The angles between the lateral sections and the central

section increase during expansion, thereby reducing or substantially eliminating length decrease of the stent due to expansion, while increasing a radial stiffness of the stent.

- 5 Preferably, each of the three sections of each web is substantially straight, the lateral sections preferably define obtuse angles with the central section, and the three sections are arranged relative to one another to form a concave or convex structure. When
10 contracted to its delivery configuration, the webs resemble stacked or nested bowls or plates. This configuration provides a compact delivery profile, as the webs are packed against one another to form web patterns resembling rows of stacked plates.
- 15 Neighboring web patterns are preferably connected to one another by connection elements preferably formed as straight sections. In a preferred embodiment, the connection elements extend between adjacent web patterns from the points of interconnection
20 between neighboring webs within a given web pattern. The orientation of connection elements between a pair of neighboring web patterns preferably is the same for all connection elements disposed between the pair. However, the orientation of connection elements alternates between
25 neighboring pairs of neighboring web patterns. Thus, a stent illustratively flattened and viewed as a plane provides an alternating orientation of connection elements between the neighboring pairs: first upwards, then downwards, then upwards, etc.

As will be apparent to one of skill in the art, positioning, distribution density, and thickness of connection elements and adjoining webs may be varied to provide stents exhibiting characteristics tailored to 5 specific applications. Applications may include, for example, use in the coronary or peripheral (e.g. renal) arteries. Positioning, density, and thickness may even vary along the length of an individual stent in order to vary flexibility and radial stiffness characteristics 10 along the length of the stent.

Stents of the present invention preferably are flexible in the delivery configuration. Such flexibility beneficially increases a clinician's ability to guide the stent to a target site within a patient's vessel. 15 Furthermore, stents of the present invention preferably exhibit high radial stiffness in the deployed configuration. Implanted stents therefore are capable of withstanding compressive forces applied by a vessel wall and maintain vessel patency. The web structure described 20 hereinabove provides the desired combination of flexibility in the delivery configuration and radial stiffness in the deployed configuration. The combination further may be achieved, for example, by providing a stent having increased wall thickness in a first portion 25 of the stent and decreased wall thickness with fewer connection elements in an adjacent portion or portions of the stent.

Depending on the material of fabrication, a stent of the present invention may be either self- 30 expanding or expandable by other suitable means, for

example, using a balloon catheter. Self-expanding embodiments preferably are fabricated from a superelastic material, such as a nickel-titanium alloy. Regardless of the expansion mechanism used, the beneficial aspects of 5 the present invention are maintained: reduced shortening upon expansion, high radial stiffness, and a high degree of flexibility.

Stents of the present invention may comprise curvature adapted to match the curvature of an 10 implantation site within a patient's body lumen or orifice, for example, adapted to match the curvature of a tortuous blood vessel. Curvature matching is expected to reduce potentially harmful restoring forces that are applied to tortuous anatomy by prior art stents. Such 15 restoring forces may cause local irritation of cells due to force concentration. The forces also may cause vessel kinking, which reduces luminal diameter and blood flow, while increasing blood pressure and turbulence.

Curvature may be imparted to the stents by a 20 variety of techniques, such as by heat treating the stents while they are arranged with the desired curvature, or plastically deforming the stents to a curved configuration with secondary apparatus, e.g. a curved balloon.

25 Methods of using stents in accordance with the present invention are also provided.

Brief Description of the Drawings

The above and other objects and advantages of the present invention will be apparent upon consideration

of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference numerals refer to like parts throughout, and in which:

5 FIG. 1 is a schematic isometric view illustrating the basic structure of a stent according to the present invention;

10 FIG. 2 is a schematic view illustrating a web structure of a wall of the stent of FIG. 1 in a contracted delivery configuration;

FIG. 3 is a schematic view illustrating the web structure of the stent of FIG. 1 in an expanded deployed configuration;

15 FIG. 4 is an enlarged schematic view of the web structure in the delivery configuration;

FIG. 5 is a schematic view of an alternative web structure of the stent of FIG. 1 having transition sections and shown in an as-manufactured configuration;

20 FIGS. 6A and 6B are, respectively, a schematic view and a detailed view of an alternative embodiment of the web structure of FIG. 5;

FIGS. 7A-7D are, respectively, a schematic view and detailed views of another alternative embodiment of the web structure of the stent of the present invention, 25 and a cross-sectional view of the stent;

FIGS. 8A and 8B are schematic views of further alternative embodiments of the stent of the present application having different interconnection patterns;

FIGS. 9A and 9B are, respectively, a schematic and a detailed view of yet another alternative embodiment of the web structure of FIG. 5;

FIGS. 10A-10D are side views, partially in section, illustrating a method of deploying a balloon expandable stent constructed in accordance with the present invention;

FIG. 11 is a side view of a self-expanding stent of the present invention having a curvature relative to a longitudinal axis of the stent;

FIG. 12 is a side view of the stent of FIG. 11 disposed within a delivery catheter;

FIGS. 13A-13C are side views, partially in section, illustrating a method of deploying the stent of FIG. 11 within tortuous anatomy;

FIG. 14 is a schematic view of an optional intravascular ultrasound image provided for positioning of the stent of FIG. 11; and

FIGS. 15A and 15B are side-views of secondary balloon apparatus for imposing curvature on a balloon-expandable stent of the present invention, shown, respectively, in a collapsed delivery configuration, and in an expanded deployed configuration.

Detailed Description Of The Invention

Referring to FIG. 1, stent 1 comprises tubular flexible body 2. Tubular flexible body 2, in turn, comprises wall 3 having a web structure, as described hereinbelow with respect to FIGS. 2-9. Stent 1 and its web structure are expandable from a contracted delivery

configuration to an expanded deployed configuration. Depending on the material of fabrication, stent 1 may be either self-expanding or expandable using a balloon catheter or other apparatus. If self-expanding, the web 5 structure is preferably fabricated from a superelastic material, such as a nickel-titanium alloy. Furthermore, stent 1 preferably is fabricated from biocompatible or biodegradable materials. It also may be radiopaque to facilitate delivery, and it may comprise an external 10 coating C that retards thrombus formation or restenosis within a vessel. The coating alternatively may deliver therapeutic agents into the patient's blood stream.

With reference to FIGS. 2-4, a first embodiment of the web structure of stent 1 is described. In FIGS. 15 2-4, wall 3 of body 2 of stent 1 is shown flattened into a plane for illustrative purposes. FIG. 2 shows web structure 4 in a contracted delivery configuration, with line L indicating the longitudinal axis of the stent. Web structure 4 comprises neighboring web patterns 5 and 20 6 arranged in alternating, side-by-side fashion. Thus, the web patterns seen in FIG. 2 are arranged in the sequence 5, 6, 5, 6, 5, etc.

FIG. 2 illustrates that web patterns 5 comprise adjoining webs 9 (concave up in FIG. 2), while web 25 patterns 6 comprise adjoining webs 10 (convex up in FIG. 2). Each of these webs has a concave or convex shape resulting in a stacked plate- or bowl-like appearance when the stent is contracted to its delivery configuration. Webs 9 of web patterns 5 are rotated 180

degrees with respect to webs 10 of web patterns 6, i.e., alternating concave and convex shapes. The structure of webs 9 and 10 is described in greater detail hereinbelow with respect to FIG. 4.

5 Neighboring web patterns 5 and 6 are interconnected by connection elements 7 and 8. A plurality of connection elements 7 and 8 are provided longitudinally between each pair of web patterns 5 and 6. Multiple connection elements 7 and 8 are disposed in the
10 circumferential direction between adjacent webs 5 and 6. The position, distribution density, and thickness of these pluralities of connection elements may be varied to suit specific applications in accordance with the present invention.

15 Connection elements 7 and 8 exhibit opposing orientation. However, all connection elements 7 have the same orientation that, as seen in FIG. 2, extends from the left side, bottom, to the right side, top. Likewise, all connection elements 8 have the same orientation that
20 extends from the left side, top, to the right side, bottom. Connection elements 7 and 8 alternate between web patterns 5 and 6, as depicted in FIG. 2.

FIG. 3 illustrates the expanded deployed configuration of stent 1, again with reference to a portion of web structure 4. When stent 1 is in the expanded deployed configuration, web structure 4 provides stent 1 with high radial stiffness. This stiffness enables stent 1 to remain in the expanded configuration while, for example, under radial stress. Stent 1 may
30 experience application of radial stress when, for

example, implanted into a hollow vessel in the area of a stenosis.

FIG. 4 is an enlarged view of web structure 4 detailing a portion of the web structure disposed in the contracted delivery configuration of FIG. 2. FIG. 4 illustrates that each of webs 9 of web pattern 5 comprises three sections 9a, 9b and 9c, and each of webs 10 of web pattern 6 comprises three sections 10a, 10b and 10c. Preferably, each individual section 9a, 9b, 9c, 10a, 10b and 10c, has a straight configuration.

Each web 9 has a central section 9b connected to lateral sections 9a and 9c, thus forming the previously mentioned bowl- or plate-like configuration. Sections 9a and 9b enclose obtuse angle α . Likewise, central section 9b and lateral section 9c enclose obtuse angle β . Sections 10a-10c of each web 10 of each web pattern 6 are similarly configured, but are rotated 180 degrees with respect to corresponding webs 9. Where two sections 9a or 9c, or 10a or 10c adjoin one another, third angle γ is formed (this angle is zero where the stent is in the fully contracted position, as shown in FIG. 4).

Preferably, central sections 9b and 10b are substantially aligned with the longitudinal axis **L** of the tubular stent when the stent is in the contracted delivery configuration. The angles between the sections of each web increase in magnitude during expansion to the deployed configuration, except that angle γ , which is initially zero or acute, approaches a right angle after

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deployment of the stent. This increase provides high radial stiffness with reduced shortening of the stent length during deployment. As will of course be understood by one of ordinary skill, the number of 5 adjoining webs that span a circumference of the stent preferably is selected corresponding to the vessel diameter in which the stent is intended to be implanted.

FIG. 4 illustrates that, with stent 1 disposed in the contracted delivery configuration, webs 9 adjoin 10 each other in an alternating fashion and are each arranged like plates stacked into one another, as are adjoining webs 10. FIG. 4 further illustrates that the configuration of the sections of each web applies to all of the webs, which jointly form web structure 4 of wall 3 15 of tubular body 2 of stent 1. Webs 9 are interconnected within each web pattern 5 via rounded connection sections 12, of which one connection section 12 is representatively labeled. Webs 10 of each neighboring web pattern 6 are similarly configured.

20 FIG. 4 also once again demonstrates the arrangement of connection elements 7 and 8. Connection elements 7, between a web pattern 5 and a neighboring web pattern 6, are disposed obliquely relative to the longitudinal axis **L** of the stent with an orientation **A**, 25 which is the same for all connection elements 7. Orientation **A** is illustrated by a straight line that generally extends from the left side, bottom, to the right side, top of FIG. 4. Likewise, the orientation of all connection elements 8 is illustrated by line **B** that

generally extends from the left side, top, to the right side, bottom of FIG. 4. Thus, an alternating **A**, **B**, **A**, **B**, etc., orientation is obtained over the entirety of web structure 4 for connection elements between neighboring 5 web patterns.

Connection elements 7 and 8 are each configured as a straight section that passes into a connection section 11 of web pattern 5 and into a connection section 11' of web pattern 6. This is illustratively shown in 10 FIG. 4 with a connection element 7 extending between neighboring connection sections 11 and 11', respectively. It should be understood that this represents a general case for all connection elements 7 and 8.

Since each web consists of three interconnected 15 sections that form angles α and β with respect to one another, which angles are preferably obtuse in the delivery configuration, expansion to the deployed configuration of FIG. 3 increases the magnitude of angles α and β . This angular increase beneficially provides 20 increased radial stiffness in the expanded configuration. Thus, stent 1 may be flexible in the contracted delivery configuration to facilitate delivery through tortuous anatomy, and also may exhibit sufficient radial stiffness in the expanded configuration to ensure vessel patency, 25 even when deployed in an area of stenosis. The increase in angular magnitude also reduces and may even substantially eliminate length decrease of the stent due to expansion, thereby decreasing a likelihood that stent

1 will not completely span a target site within a patient's vessel post-deployment.

The stent of FIG. 4 is particularly well suited for use as a self-expanding stent when manufactured, for example, from a shape memory alloy such as nickel-titanium. In this case, web patterns 5 and 6 preferably are formed by laser-cutting a tubular member, wherein adjacent webs 9 and 10 are formed using slit-type cuts. Only the areas circumferentially located between connection members 7 and 8 (shaded area D in FIG. 4) require removal of areas of the tubular member. These areas also may be removed from the tubular member using laser-cutting techniques.

Referring now to FIG. 5, an alternative embodiment of the web structure of stent 1 is described. FIG. 5 shows the alternative web structure in an as-manufactured configuration. The basic pattern of the embodiment of FIG. 5 corresponds to that of the embodiment of FIGS. 2-4. Thus, this alternative embodiment also relates to a stent having a tubular flexible body with a wall having a web structure configured to expand from a contracted delivery configuration to the deployed configuration.

Likewise, the web structure again comprises a plurality of neighboring web patterns, of which two are illustratively labeled in FIG. 5 as web patterns 5 and 6. Web patterns 5 and 6 are again provided with adjoining webs 9 and 10, respectively. Each of webs 9 and 10 is subdivided into three sections, and reference is made to

the discussion provided hereinabove, particularly with respect to FIG. 4. As will of course be understood by one of skill in the art, the stent of FIG. 5 will have a smaller diameter when contracted (or crimped) for 5 delivery, and may have a larger diameter than illustrated in FIG. 5 when deployed (or expanded) in a vessel.

The embodiment of FIG. 5 differs from the previous embodiment by the absence of connection elements between web patterns. In FIG. 5, web patterns are 10 interconnected to neighboring web patterns by transition sections 13, as shown by integral transition section 13 disposed between sections 9c and 10c. Symmetric, inverted web patterns are thereby obtained in the region of transition sections 13. To enhance stiffness, 15 transition sections 13 preferably have a width greater than twice the width of webs 9 or 10.

As seen in FIG. 5, every third neighboring pair of webs 9 and 10 is joined by an integral transition section 13. As will be clear to those of skill in the 20 art, the size and spacing of transition sections 13 may be altered in accordance with the principles of the present invention.

An advantage of the web structure of FIG. 5 is that it provides stent 1 with compact construction 25 coupled with a high degree of flexibility in the delivery configuration and high load-bearing capabilities in the deployed configuration. Furthermore, FIG. 5 illustrates that, as with connection elements 7 and 8 of FIG. 4, transition sections 13 have an alternating orientation 30 and are disposed obliquely relative to the longitudinal

axis of the stent (shown by reference line **L**). FIG. 5 also illustrates that, especially in the deployed configuration, an H-like configuration of transition sections 13 with adjoining web sections is obtained.

5 The stent of FIG. 5 is well suited for use as a balloon-expandable stent, and may be manufactured from stainless steel alloys. Unlike the stent of FIG. 4, which is formed in the contracted delivery configuration, the stent of FIG. 5 preferably is formed in a partially
10 deployed configuration by removing the shaded areas **D'** between webs 9 and 10 using laser-cutting or chemical etching techniques. In this case, central sections 9b and 10b are substantially aligned with the longitudinal axis **L** of the stent when the stent is crimped onto the
15 dilatation balloon of a delivery system.

Referring now to FIGS. 6 and 7, alternative embodiments of the web structure of FIG. 5 are described. These web structures differ from the embodiment of FIG. 5 in the spacing of the transition sections. Web structure
20 15 of FIGS. 6A and 6B provides a spacing of transition sections 16 suited for use in the coronary arteries. FIG. 6A shows the overall arrangement, while FIG. 6B provides a detail view of region A of FIG. 6A. Other arrangements and spacings will be apparent to those of
25 skill in the art and fall within the scope of the present invention.

Web structure 17 of FIGS. 7A-7D provides stent 1 with a variable wall thickness and a distribution density or spacing of transition sections 16 suited for

use in the renal arteries. FIG. 7A shows the arrangement of web structure 17 along the length of stent 1, and demonstrates the spacing of transition sections 18. FIGS. 7C and 7D provide detail views of regions A and B, 5 respectively, of FIG. 7A, showing how the spacing and shape of the webs that make up web structure 17 change as stent 1 changes along its length. In particular, as depicted (not to scale) in FIG. 7D, stent 1 has first thickness t_1 for first length L_1 and second thickness t_2 , 10 for second length L_2 .

The variation in thickness, rigidity and number of struts of the web along the length of the stent of FIGS. 7A-7D facilitates use of the stent in the renal arteries. For example, the thicker region L_1 includes 15 more closely spaced and sturdier struts to provide a high degree of support in the ostial region, while the thinner region L_2 includes fewer and thinner struts to provide greater flexibility to enter the renal arteries. For such intended applications, region L_1 preferably has a 20 length of about 6-8 mm and a nominal thickness t_1 of 0.21 mm, and region L_2 has a length of about 5 mm and a nominal thickness t_2 of about 0.15 mm.

As depicted in FIGS. 7A-7D, the reduction in wall thickness may occur as a step along the exterior of 25 the stent, such as may be obtained by grinding or chemical etching. One of ordinary skill in the art will appreciate, however, that the variation in thickness may occur gradually along the length of the stent, and that the reduction in wall thickness could be achieved by

alternatively removing material from the interior surface of the stent, or both the exterior and interior surfaces of the stent.

In FIGS. 8A and 8B, additional embodiments of web structures of the present invention, similar to FIG. 5, are described; in which line L indicates the direction of the longitudinal axis of the stent. In FIG. 5, every third neighboring pair of webs is joined by an integral transition section 13, and no set of struts 9a-9c or 10a-10c directly joins two transition sections 13. In the embodiment of FIG. 8A, however, integral transition sections 20 are arranged in a pattern so that the transition sections span either four or three adjacent webs. For example, the portion indicated as 22 in FIG. 15 8A includes three consecutively joined transition sections, spanning four webs. In the circumferential direction, portion 22 alternates with the portion indicated at 24, which includes two consecutive transition sections, spanning three webs.

By comparison, the web pattern depicted in FIG. 8B includes only portions 24 that repeat around the circumference of the stent, and span only three webs at a time. As will be apparent to one of ordinary skill, other arrangements of integral transition regions 13 may 25 be employed, and may be selected on an empirical basis to provide any desired degree of flexibility and trackability in the contracted delivery configuration, and suitable radial strength in the deployed configuration.

Referring now to FIGS. 9A and 9B, a further alternative embodiment of the stent of FIG. 8B is described, in which the transition sections are formed with reduced thickness. Web structure 26 comprises 5 transition sections 27 disposed between neighboring web patterns. Sections 27 are thinner and comprise less material than transition sections 20 of the embodiment of FIG. 8B, thereby enhancing flexibility without significant reduction in radial stiffness.

10 Referring now to FIGS. 10A-10D, a method of using a balloon expandable embodiment of stent 1 is provided. Stent 1 is disposed in a contracted delivery configuration over balloon 30 of balloon catheter 32. As seen in FIG. 10A, the distal end of catheter 32 is 15 delivered to a target site **T** within a patient's vessel **V** using, for example, well-known percutaneous techniques. Stent 1 or portions of catheter 32 may be radiopaque to facilitate positioning within the vessel. Target site **T** may, for example, comprise a stenosed region of vessel **V** 20 at which an angioplasty procedure has been conducted.

In FIG. 10B, balloon 30 is inflated to expand stent 1 to the deployed configuration in which it contacts the wall of vessel **V** at target site **T**. Notably, the web pattern of stent 1 described hereinabove 25 minimizes a length decrease of stent 1 during expansion, thereby ensuring that stent 1 covers all of target site **T**. Balloon 30 is then deflated, as seen in FIG. 10C, and balloon catheter 32 is removed from vessel **V**, as seen in FIG. 10D.

Stent 1 is left in place within the vessel. Its web structure provides radial stiffness that maintains stent 1 in the expanded configuration and minimizes restenosis. Stent 1 may also comprise external 5 coating C configured to retard restenosis or thrombosis formation around the stent. Coating C may alternatively deliver therapeutic agents into the patient's blood stream.

With reference to FIG. 11, an alternative 10 embodiment of stent 1 is described. Prior art stents are commonly formed with substantially straight longitudinal axes. When such a stent is implanted within a tortuous blood vessel, i.e. a blood vessel that does not have a straight longitudinal axis, either the stent or the 15 vessel (or both) deforms to match the profile of the vessel or stent, respectively.

Since previously known self-expanding stents are somewhat flexible, they generally deform at least partially to the curvature of the vessel. However, 20 notably near their ends, these stents also apply localized restoring forces to the wall of the vessel that act to straighten the vessel in the vicinity of the implantation site. As previously known balloon-expandable stents tend to exert higher radial forces, 25 they may apply restoring forces that cause tortuous anatomy to assume the substantially straight profiles of the stents.

For both self-expanding and balloon-expandable embodiments, in circumstances where the vessel wall is

thinned or brittle, restoring forces may cause acute puncture or dissection of the vessel, potentially jeopardizing the health of the patient. Alternatively, the restoring forces may cause localized vessel
5 irritation, or may remodel the vessel over time such that it more closely tracks the unstressed, straight profile of the stent. Such remodeling may alter blood flow characteristics through the vessel in unpredictable ways. Restoring forces also may kink the vessel, reducing
10 luminal diameter and blood flow, while increasing blood pressure and turbulence. These and other factors may increase a risk of stenosis or thrombus formation, as well as vessel occlusion.

In FIG. 11, apparatus in accordance with the
15 present invention is provided that is expected to reduce potentially harmful restoring forces applied to tortuous anatomy by prior art stents. Stent 40 comprises curvature **Cu** in an expanded deployed configuration. Stent 40 also illustratively comprises web structure 4
20 described hereinabove; however, other structures will be apparent to those of skill in the art. The web structure may be formed, for example, by laser-cutting a tubular member, as discussed previously.

Stent 40 comprising curvature **Cu** is preferably
25 self-expanding or balloon-expandable. However, Biflex, wire mesh, and other embodiments will be apparent to those of skill in the art, and fall within the scope of the present invention. Self-expanding embodiments of stent 40 are preferably fabricated from a superelastic

material, such as a nickel-titanium alloy, e.g.

"Nitinol". Balloon-expandable embodiments may comprise, for example, a stainless steel.

- Curvature **Cu** of stent 40 is configured to match
- 5 the curvature of an implantation site within a patient's body lumen or body orifice, for example, adapted to match the curvature of a tortuous blood vessel. Thus, when implanted within the vessel, neither the vessel nor the stent need deform to match the other's profile.
 - 10 Curvature matching is thereby expected to reduce localized restoring forces at the implantation site. Curvature may be imparted to stent 40 by a variety of techniques, such as by heat treating the stent while it is arranged with the desired curvature, or by plastically
 - 15 deforming the stent with secondary apparatus, e.g. a curved balloon.

- Matching of curvature **Cu** with the internal profile of a blood vessel or other body lumen may be accomplished by mapping the internal profile of the body
- 20 lumen, preferably in 3-dimensional space. Then, curvature **Cu** of stent 40 may be custom-formed accordingly, e.g. by heat treating the stent. Alternatively, secondary apparatus, such as a balloon catheter, may be custom-formed and adapted for
 - 25 plastically deforming stent 40 to impose the curvature. Mapping of the body lumen may be accomplished using a variety of techniques, including ultrasound, e.g. B-mode ultrasound examination, intravascular ultrasound ("IVUS"), angiography, radiography, magnetic resonance

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imaging ("MRI"), computed tomography ("CT"), and CT angiography.

As an alternative to custom-forming the curvature of stent 40 or the curvature of secondary apparatus for plastically deforming stent 40, a statistical curvature matching technique may be used. Stent 40 or the secondary apparatus may be provided with a standardized curvature C_u that more closely matches an average curvature for a desired body lumen within a specific patient population, as compared to prior art stents. As with custom matching, statistical matching of the curvature may be facilitated or augmented by pre-mapping the intended implantation site.

As a further alternative, stent 40 may be manufactured and stocked in a number of different styles, each having its own predetermined curvature. In this manner, a clinician may select a stent having a degree of curvature most appropriate for the specific anatomy presented by the case at hand.

Beneficially, the present invention provides flexibility in providing stents having a wide variety of curvatures/tortuosities, as needed, as will be apparent to those of skill in the art. Stent 40 is expected to have specific utility at tortuous vessel branchings, for example, within the carotid arteries.

Referring now to FIG. 12, a self-expanding embodiment of stent 40, having pre-imposed curvature in the deployed configuration, is shown in a collapsed delivery configuration within delivery catheter 50.

Catheter 50 comprises inner sheath 52 having a guide wire lumen, and outer sheath 54 having a lumen sized for disposal about inner sheath 52. Sheath 52 comprises section 56 of reduced cross section. Stent 40 is

5 collapsed about section 56 of inner sheath 52 between optional radiopaque marker bands 58, such that the stent is flush with the remainder of the inner sheath. Marker bands 58 facilitate longitudinal positioning of stent 40 at an implantation site. Outer sheath 54 is disposed

10 over inner sheath 52 and stent 40, in order to maintain the stent in the collapsed delivery configuration. Sheaths 52 and 54 straighten stent 40 while it is in the delivery configuration, thereby facilitating delivery of the stent to an implantation site.

15 Delivery catheter 50 optionally may comprise imaging transducer 60 that facilitates radial positioning of stent 40, i.e. that facilitates *in vivo* radial alignment of curvature **Cu** of stent 40 with the internal profile of the implantation site. Imaging transducer 60

20 preferably comprises an IVUS transducer that is coupled to a corresponding imaging system, as described hereinbelow with respect to FIG. 14. An IVUS transducer similar to transducer 60 optionally may also be used to 3-dimensionally map the internal profile of the

25 implantation site prior to advancement of stent 40, thereby allowing custom-manufacture of stent 40.

With reference now to FIGS. 13, a method of using the self-expanding embodiment of stent 40 within tortuous anatomy at a vessel branching is described. In

FIGS. 13, stent 40 is illustratively disposed within a patient's carotid arteries, but other implantation sites will be apparent to those of skill in the art. As seen in FIG. 13A, delivery catheter 50, having stent 40 disposed thereon in the collapsed delivery configuration, is advanced over guide wire 70 to an implantation site within internal carotid artery **ICA** that spans the branching of external carotid artery **ECA**. The implantation site may comprise a stenosed or otherwise damaged portion of the artery.

Stent 40 has a curvature **Cu** in the expanded deployed configuration of FIG. 11 that tracks the internal profile of internal carotid artery **ICA** at the implantation site. As discussed previously, curvature **Cu** may be custom-formed, statistically chosen, or selected from a number of pre-manufactured shapes to better track the curvature of the artery. Such selection may be facilitated or augmented by mapping the profile of the **ICA**, using techniques described hereinabove.

In order to properly align curvature **Cu** of stent 40 with the internal profile of the implantation site within internal carotid artery **ICA**, optional radiopaque marker bands 58 and optional imaging transducer 60 of delivery catheter 50 may respectively be used to longitudinally and radially position stent 40 at the implantation site. Longitudinal positioning of stent 40 may be accomplished by imaging radiopaque marker bands 58, e.g. with a fluoroscope. The implantation site is

then positioned between the marker bands, thereby longitudinally orienting stent 40.

Referring to FIG. 14, in conjunction with FIGS. 13, a technique for radial positioning is described.

5 Imaging transducer 60 preferably comprises an IVUS transducer. Transducer 60 may be either a forward-looking IVUS transducer, or a standard radial-looking IVUS transducer. FIG. 14 provides illustrative IVUS image 80, collected from transducer 60.

10 In FIG. 14, when using a forward-looking IVUS transducer 60, lumen **L** of internal carotid artery **ICA** can be seen curving away from the longitudinal axis of transducer 60 of delivery catheter 50. Reference line **R** has been superimposed on image 80 and corresponds to the 15 axis of curvature of stent 40. Thus, rotation of catheter 50, and thereby transducer 60 and stent 40, causes rotation of reference line **R** within image 80. In order to radially orient stent 40 with respect to the implantation site, reference line **R** is aligned with lumen 20 **L**.

Referring still to FIG. 14, when using a standard radial-looking IVUS transducer 60, side-branching external carotid artery **ECA** may be imaged. By comparing the position of the external carotid in the 25 IVUS image of FIG. 14 to its position in the fluoroscopic images of FIGS. 13, catheter 50 may be rotated to radially align reference line **R** relative to the position of external carotid artery **ECA** in FIGS. 13, thereby

radially aligning curvature **Cu** of stent 40 with the curvature of internal carotid artery **ICA**.

As an alternative technique, both longitudinal and radial positioning of stent 40 may be performed with transducer 60. This is accomplished by creating a 3-dimensional map of the implantation site with transducer 60, by collecting and stacking a series of cross-sectional IVUS images taken along the length of the implantation site. Stent 40 is then positioned with respect to this map. If the vessel was mapped prior to delivery of catheter 50 and stent 40, longitudinal positioning may be accomplished by referencing IVUS image 80 with the previously-conducted mapping, and by advancing catheter 50 until image 80 matches the cross-section of the previous mapping at the proper location.

As yet another technique, both longitudinal and radial positioning of stent 40 may be achieved with radiopaque marker bands 58. Longitudinal positioning may be achieved as described previously, while radial positioning may be achieved by varying the radiopacity of the bands about their circumference, such that the bands comprise a visually recognizable alteration in radiopacity along the axis of curvature of stent 40. This alteration in radiopacity is aligned with the axis of curvature of the implantation site.

Referring back now to FIGS. 13, in FIG. 13B, once stent 40 has been radially and longitudinally oriented with respect to internal carotid artery **ICA**, outer sheath 54 of delivery catheter 50 is gradually

withdrawn with respect to inner sheath 52. Stent 40 self-expands to the deployed configuration, and delivery catheter 50 and guide wire 70 are removed from the artery, as in FIG. 13C. Curvature **Cu** of stent 40 tracks 5 the internal profile of internal carotid artery **ICA**, thereby reducing restoring forces applied to the vessel.

With reference to FIGS. 15, secondary apparatus in accordance with the present invention for applying curvature to a balloon-expandable embodiment of stent 40 10 is described. Secondary apparatus 100 comprises balloon catheter 102 having balloon 104. Secondary apparatus 102 also preferably comprises guide wire lumen 106, as well as radiopaque marker bands 58 and imaging transducer 60, as described hereinabove with respect to FIGS. 13 and 14. 15 Balloon 104, and by extension secondary apparatus 100, is substantially straight in the collapsed delivery configuration of FIG. 15A, but comprises curvature **Cu** in the expanded deployed configuration of FIG. 15B.

Curvature **Cu** may be applied to balloon 104 20 using techniques described hereinabove. For example, balloon 104 may be heat-treated while the balloon is arranged with the desired curvature. Heat treating of balloon 104 may be accomplished while the balloon is in either the delivery or deployed configuration, or while 25 the balloon is in an intermediary configuration.

Additionally, curvature **Cu** of balloon 104 may be matched to the internal profile of a treatment site using, for example, custom-matching or statistical-matching techniques, as described previously.

Embodiments of stent 40 for use with the apparatus of FIGS. 15 are preferably manufactured without curvature **Cu**, and may comprise, for example, stent 1 of FIGS. 1-10. As will be clear to those of skill in the art, a balloon-expandable embodiment of stent 40 may be crimped onto balloon 104 while the balloon is in the collapsed delivery configuration. When the balloon is expanded to the deployed configuration at a tortuous treatment site within a patient, curvature **Cu** of balloon 104 plastically deforms stent 40 and imposes curvature **Cu** on the stent. Alignment of curvature **Cu** with the curvature of the tortuous anatomy may be accomplished using, for example, techniques described hereinabove with respect to FIGS. 13 and 14. Thus, a method for placing profile-matched balloon-expandable stents in tortuous anatomy is clear to those of skill in the art from FIGS. 10 in conjunction with FIGS. 13 and 14.

Although preferred illustrative embodiments of the present invention are described hereinabove, it will be evident to one skilled in the art that various changes and modifications may be made therein without departing from the invention. For example, stent 40 may further comprise coating **C**, described hereinabove. Additionally, alternative embodiments of secondary apparatus 100 for plastically deforming stent 40, which do not comprise balloons, may be provided. It is intended in the appended claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.